March 10, 1998

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

Dear Dr. Yetley:

Notice is hereby given pursuant to the requirements of Section 403(r)(6)(21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING BILBERRY. FAMILY ESSENTIALS™ WITH REFERENCE TO ANY CLAIM CONCERNING BILBERRY was first marketed with these statements of nutritional support on Friday, March 6, 1998. The statements of nutritional support are as follows:

“Bilberry has been shown in extensive research to have an antioxidant effect and to contribute to overall eye health.”

“Bilberry is a European popular herb used to enhance eye health and circulation”. “Bilberry supports healthy vision”.

Bilberry (Latin name: vaccinium myrtillus), is a small shrub that grows in the forests of Northern and Central Europe. Modern research on the use of Bilberry emerged during the Second World War when British pilots noted that their night vision was improved when they ate Bilberry jam.

Numerous studies since then have determined that a bioflavonoid complex made up of anthocyanosides is primarily responsible for Bilberry’s actions on the body’s circulatory system and the retina of the eye. This Family Essentials™ for Active Seniors multivitamin contains the same standardization level of anthocyanosides as that used successfully in scientific studies.

Very truly yours,
MASON VITAMINS, INC.

Sonia C. Rodriguez
VP Marketing & Regulatory Affairs
STUDIES FOR BILBERRY CLAIMS


Coget PJ, Merlen JF., “Clinical Study of a New Chemical Agent for Vascular Protection, Difrarel 20 containing Anthocyanoside extracts from Vaccinium Myrtillus” Phlebologie; 21(2), 221-228, Apr-Jun 1968.


